

REMARKS***Summary of the Amendment***

Upon entry of the above amendment, claim 7 will have been amended and claims 1 – 6 and 8 – 23 will have been canceled without prejudice or disclaimer. Further, Applicants expressly reserve the right to refile the subject matter of claims 1 – 6 and 8 – 23 in or more continuing applications.

Request for Entry of Substitute Specification

In pending Official Action, the Examiner has rejected claims 1 – 23 over the applied art of record. By the present amendment and remarks, Applicants submit that the rejections have been overcome, and respectfully request reconsideration of the outstanding Office Action and allowance of the present application.

Rejection of Claims 1 – 6 and 8 – 23 is Moot

While Applicants do not agree that the invention recited in claims 1 – 6 and 8 – 23 are anticipated or rendered unpatentable over the applied art of record, in an effort to advance prosecution, Applicants have canceled claims 1 – 6 and 8 – 23 without prejudice or disclaimer. Further, Applicants expressly reserve the right to refile the subject matter of these canceled claims in one or more continuing applications.

Accordingly, Applicants submit that the rejections of claims 1 – 6 and 8 – 23 are moot in view of the present amendment. Moreover, Applicants request favorable consideration of independent claim 7.

Traversal of Rejection Under 35 U.S.C. § 103(a)

Applicants traverse the rejection of claim 7 under 35 U.S.C. § 103(a) as being unpatentable over WEBB et al. (U.S. Patent No. 6,629,533) [hereinafter “WEBB”]. While

acknowledging that WEBB fails to disclose anchoring pins in the shape of a helix, the Examiner asserts it would have been obvious to arrange the pins in a helix based upon an embodiment in WEBB's Fig. 4a showing a helix shaped anchoring member 338. Applicants traverse the Examiner's assertions.

With regard to the pending rejection of the claims under 35 U.S.C. § 103(a), Applicants note the Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the Examiner does not produce a *prima facie* case, Applicants are under no obligation to submit evidence of non-obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met:

- (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
- (2) there must be a reasonable expectation of success; and
- (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP §2142.

Further, while rejecting a *rigid* application of the teaching, suggestion, or motivation ("TSM") test in an obviousness inquiry, the U.S. Supreme Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination. *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-

1357 (Fed. Cir. 2007) (quoting *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731 (2007)).

Applicants' independent claim 7, as currently amended, recites, *inter alia*, a substantially cylindrical body having an external lateral wall; and flexible elements attached to the external wall structured and arranged to prevent migration so as to maintain said lachrymal plug in position, wherein the flexible elements comprise *radial pins*, and wherein the pins are *arranged in helical formation* around the body. Applicants submit that WEBB fails to suggest at least the above-noted features of the invention.

Applicants note that, while Figs. 4a and 4b show anchoring arms 338, which are formed as a "single flange helically wound about (and integral with) the shaft 312," (WEBB, Col. 5, ll. 24 and 25), WEBB further discloses that the helically wound flange is intended to guide "the punctum plug 310 into the punctal opening and aids in insertion by allowing the device to be inserted and positioned with a rotational (or screw-like) motion." (WEBB, Col. 5, ll. 42 – 44).

Applicants note that, in contrast to expressly recited features of claim 7, WEBB discloses a single flange that is helically wound around a shaft. This document provides no teaching or suggestion for replacing single flange 338 with a plurality of flexible radiating pins, as recited in claim 7, and certainly fails to suggest replacing the single flange 338 with a helical arrangement of flexible radiating pins, as is further recited in claim 7.

Applicants submit that the applied art fails to identify any articulated reasoning in the applied art of record for modifying WEBB in the manner asserted by the Examiner. Instead, the Examiner finds the rationale for modifying WEBB in the Manual of Patent Examining Procedure [hereinafter "MPEP"]. In particular, the Examiner asserts it would have been obvious to "form

in one piece an article that was previously formed in several pieces and joined together," (citing MPEP § 2144.04(V)(A)). However, Applicants submit this reasoning is directly opposite to the issue before the Examiner in the pending case. In particular, pending claim 7 recites an arrangement of several elements, i.e., flexible radiating pins arranged in a helical formation, while the applied art shows a single element, i.e., a flange helically wound around a shaft. Thus, while the Examiner has identified reasoning why it would not have been patentable to join individual elements into a one piece article, the Examiner has not identified any reasoning for the contrary, i.e., that it would have been obvious to divide the single unitary construction into a plurality of individual elements.

Further, Applicants note that, with regard to the WEBB structure of Figs. 4a and 4b, it would not have been obvious to one ordinarily skilled in the art to modify the single helically wound flange into a plurality of flexible radiating pins in a helical arrangement, as recited in claim 7, because it is not apparent that WEBB so modified would operate in its intended manner. That is, the single flange of WEBB is specially designed so the punctum plug can be screwed into the punctal opening. However, the Examiner has identified no disclosure or suggestion in the applied art to suggest that one ordinarily skilled in the art would reasonably expect the plurality of flexible pins in a helical arrangement to facilitate screwing the plug into the punctal opening, as is intended by WEBB.

In view of the foregoing, Applicants submit that no proper modification of WEBB under 35 U.S.C. § 103(a) can render unpatentable the combination of features recited in independent claim 7. Therefore, Applicants submit that the pending rejection is improper and should be withdrawn.

Accordingly, Applicants request that the Examiner reconsider and withdraw the rejection

of claim 7 under 35 U.S.C. § 103(a) and indicate that this claim is allowable.

Application is Allowable

Thus, Applicants respectfully submit that each and every pending claim of the present invention meets the requirements for patentability under 35 U.S.C. §§ 102 and 103, and respectfully request the Examiner to indicate allowance of each and every pending claim of the present invention.

Authorization to Charge Deposit Account

The undersigned authorizes the charging of any necessary fees, including any extensions of time fees required to place the application in condition for allowance by Examiner's Amendment, to Deposit Account No. 19 - 0089 in order to maintain pendency of this application.

CONCLUSION

In view of the foregoing, it is submitted that none of the references of record, either taken alone or in any proper combination thereof, anticipate or render obvious the Applicants' invention, as recited in claim 7. The applied reference of record has been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Further, any amendments to the claims which have been made in this response and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate.

Respectfully submitted,
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